Ortho-Clinical Diagnostics
a Johnson & Johnson company

1001 US HWY 202
Raritan, NJ 08869-0606

DECLARATION OF CONFORMITY

MANUFACTURER:	Ortho-Clinical Diagnostics, Inc. 1001 US Highway 202 Raritan, NJ 08869-0606 U.S.A.
AUTHORIZED REPRESENTATIVE:	Ortho-Clinical Diagnostics Johnson and Johnson 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4DP United Kingdom
PRODUCT:	Ortho AutoVue® Innova Ortho AutoVue® Ultra
CLASSIFICATION:	Non-annex II
CONFORMITY ASSESSMENT ROUTE:	Annex III

Ortho-Clinical Diagnostics, Inc. hereby declares Ortho AutoVue Innova and Ortho AutoVue Ultra meet the provisions of the Council Directive 98/79/EC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

- EN 1441: October 1997 Medical Devices – Risk Analysis
- ISO 14971: 2000 (E) Medical devices – Application of risk management to medical devices

DECLARATION OF CONFORMITY (continued)

- EN 591: March 2001 Instructions for Use for IVD Instruments for Professional Use.
- EN 1658: December 1996 Requirements for Marking of IVD instruments.
- EN 980: August 2002 Graphical symbols for use in the labeling of medical devices
- EN 61326: 1997/A1: 1998/ A2:2001 Electrical Equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.
- EN 61010-1: 2001 (2nd Edition) Safety of electrical measurement, control and laboratory equipment.
- EN /ISO 13485: 2000
- ISO 13485: 1996 Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001: 1994

PLACE, DATE OF ISSUE: Raritan, NJ, U.S.A., 9/27/04
Date

SIGNATURE:

Mizanu Kebede
Executive Director,
Quality, Regulatory, Compliance